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Mr. Alvin E. Crespo, Director  
Environmental Health and Safety  
Bristol-Myers Squibb Manufacturing Company  
Humacao Operations  
P.O. Box 609  
Humacao, Puerto Rico, 00792-1255

Re: Acceptance of response to EPA comments to the February 2016 Release Assessment  
Report for the Bristol-Myers Squibb Manufacturing Company, Humacao, Puerto Rico  
EPA ID Number: PRD 090021056

Dear Mr. Crespo:

The United States Environmental Protection Agency-Region 2 (EPA) has reviewed your response to the EPA comments provided on the letter dated September 15, 2016 (Response) regarding the February 26, 2016 Release Assessment Report (RAR) for the Bristol-Myers Squibb Manufacturing Company (BMSMC) in Humacao, Puerto Rico.

EPA has determined that the responses are acceptable and all our concerns have been adequately addressed and incorporated into the Final RAR dated November 21, 2016. If you have any questions regarding this correspondence, please contact Socorro Martinez of my staff at (787) 977-5886 or via email at [martinez.socorro@epa.gov](mailto:martinez.socorro@epa.gov).

Sincerely,

Carmen Guerrero, Director  
Caribbean Environmental Protection Division

cc: Manuel O. Claudio Rodriguez, Manager,  
Land Pollution Control Program, PREQB

**TECHNICAL REVIEW  
RESPONSE TO US EPA COMMENTS  
ON THE  
FEBRUARY 2016 RELEASE ASSESSMENT REPORT**

**BRISTOL MYERS SQUIBB MANUFACTURING COMPANY  
HUMACAO, PUERTO RICO**

**I. INTRODUCTION**

EPA has complete the review and found that that all responses are acceptable and all edits were adequately incorporated into the Final RAR. The original U.S.EPA comments and BMSMC responses are repeated below for clarity.

**II. GENERAL COMMENTS**

1. Although the current use of the BMSMC facility is industrial/commercial and a future deed restriction may ensure that remains the case, the soil and groundwater data also should be compared to the residential RSLs because of the potential for off- site migration of groundwater contamination. Soil and groundwater contamination with the potential for off-site impacts (e.g., groundwater contamination located immediately adjacent to the downgradient site perimeter, soil contamination above impact to groundwater levels at the downgradient site boundary, contamination associated with potential vapor intrusion into off-site residences) must be characterized to residential RSLs. Revise the RAR accordingly, and ensure that the draft SAP for each phase of investigation reflects this important risk consideration.

**BMSMC Response:**

Applicable residential screening levels have been added to the appropriate tables in the Final Release Assessment Report.<sup>1</sup> In addition, the 2016 Puerto Rico Water Quality Standards have been added to the appropriate tables. The text has also been revised to incorporate these changes.

COPCs that exceed residential screening levels but not commercial screening levels have been identified and added to appropriate text and tables in the revised Final Release Assessment Report.

**U.S. EPA Response:**

The response to this comment is acceptable.

2. According to Footnote 4 on page 7, detected compounds for which no EPA screening levels are available will be carried forward into the SAP for further investigation and evaluation. This is an important point which clarifies the scope of the follow-up field investigation effort and deserves more than a minor mention in a footnote. Expand Section 5 of the RAR to include, and expand on this footnote, and include a list of all detected compounds for which no screening levels are available.

**BMSMC Response:**

Section 5 has been revised to include a discussion on detected compounds for which no USEPA screening levels or PRWQS are available and new **Table 15** has been added to include a list of these compounds.

**U.S. EPA Response:**

The response to this comment is acceptable.

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<sup>1</sup> Tables in the Final Release Assessment Report that contain USEPA action levels have been updated to the May 2016 USEPA regional screening levels.

3. The RAR only vaguely describes the issue that prompted the preliminary reevaluation of historic sampling results, the process utilized for the review, and recommendations to avoid these issues in the future. Expand the RAR to include more detail such that the original failings are clearly described, a robust root cause analysis is provided, and recommendations to avoid similar issues in the future.

**BMSMC Response:**

BMSMC has retained outside counsel to conduct an assessment of the factual circumstances necessitating the reevaluation of historical sampling results and the ultimate submission by BMSMC to EPA of the January 26, 2016 Notification of Potential Newly Identified Release letter and the February 15, 2016 RAR, including the potentially premature reduction in the target analyte list.

As of the date of this letter, BMSMC's assessment is ongoing. Our goal is to complete the assessment by early next year.

BMSMC is committed to cooperating with EPA and will provide an update to the agency when the assessment is complete. BMSMC will further share with EPA any remedial measures and/or other recommendations deemed appropriate in light of the findings.

**U.S. EPA Response:**

The response to this comment is acceptable.

4. The RA does not currently include figures showing sampling results for the new potential COCs. However, a spatial representation of the locations where the maximum detected concentrations were found (relative to SWMUs and BMSMC facility property boundaries) would shed light on potential source areas and contaminant delineation. Expand the RAR to include figures showing the location of maximum detected concentrations in each medium for each detected COC.

**BMSMC Response:**

New figures have been added to the RAR that indicate the location of the maximum concentration of each additional compound detected in groundwater (**Figure 3**), soil (**Figure 4**), soil gas (**Figure 5**) and indoor air (**Figure 6**) at each of the three SWMUs (Building 5 Area, Former Tank Farm Area, and the Former Brule Incinerator Area).



**U.S. EPA Response:**

The response to this comment is acceptable.

5. Attachments A and B present a summary of detections identified in the groundwater data for Building 5 and the Former Tank Farm area. This information should be expanded to include a summary of detections in each data set (groundwater, soil, soil gas, and indoor air). This information should then be incorporated into the RAR per se, rather than provided as an electronic attachments to the RAR copies.

**BMSMC Response:**

The tables in the RAR have been revised to include the number of samples, number of detects, and maximum detected concentration for each additional compound detected in groundwater, soil, soil gas, and indoor air.

**U.S. EPA Response:**

The response to this comment is acceptable.

## **II. SPECIFIC COMMENTS**

### ***Section 2.2, Current Operations, Pages 5 and 6***

1. The second paragraph in this section details current manufacturing processes and support operations at the BMSMC facility. Expand the text to indicate that the Tank Farm is located at the North Tank Farm (SWMU 3a) and that the one remaining RCRA-permitted liquid hazardous waste storage tank (Tank T-901) is located at the Hazardous Waste Management Facility (HWMF). Revise Figure 2 to show the location of these active facility features, and to note that the Brule Incinerator was formerly located at the HWMF.

**BMSMC Response:**

Section 2.2 has been expanded to include a description of the location of the North/Renasa Tank Farm (SWMU 3a) and the RCRA permitted liquid hazardous waste storage tank (T-901). The locations of the North/Renasa Tank Farm, Tank T-901, and the former Brule Incinerator have been added to **Figure 2**.

**U.S. EPA Response:**

The response to this comment is acceptable.

### ***Section 3.2.2, FTF Area Soil Assessment, Page 12***

2. Footnote 8 indicates that total petroleum hydrocarbon - gasoline range organics (TPH-GRO) and total petroleum hydrocarbons - diesel range organics (TPH- DRO) results were compared to the TPH (Aromatic Low) and TPH (Aromatic Medium) RSLs, respectively. However, because the Aliphatic Medium RSLs are lower than the Aromatic Medium RSLs, that set should be used for comparison with the TPH-DRO results. Revise the RAR and its conclusions accordingly, and ensure that any changes in the scope of potential COCs is accurately represented in the SAPs for Phase 1 and 2A.

**BMSMC Response:**

Footnote 7 (former Footnote 8) and **Table 7** have been revised to indicate TPH-DRO analytical results will be compared to the Aliphatic Medium RSLs. In addition, the text and tables have been updated with the May 2016 USEPA RSLs.

**U.S. EPA Response:**

The response to this comment is acceptable.

***Section 3.3.2, Brule Soil Assessment, Page 15***

3. Footnote 11 lists several potential COCs that would be eliminated from further consideration if a dilution attenuation factor (DAF) of 20 was applied to the protection of groundwater screening level. The DAF represents the reduction in concentration that occurs as soil leachate moves through soil and groundwater, and contaminant mass is adsorbed, degraded, and diluted by clean groundwater. While it may be appropriate to consider application of a DAF later as part of risk evaluation, we believe that it is inadvisable to restrict the target analyte list at this time. We further note that BMSMC has retained these potential COCs for further investigation (as per Table 14) and will confirm that these potential COCs are addressed in the SAP upon receipt. These COCs should not be eliminated without EPA approval.

**BMSMC Response:**

Footnote 11 has been deleted from Section 3.3.2. The application of a DAF will be considered as part of the Human Health Risk Assessment which will be included in the revised Corrective Measures Study Report.

For consistency, the same footnote (Footnote 7 in the February 2016 Release Assessment Report) in Section 3.1.2 Building 5 Area Soil Assessment has been deleted.

**U.S. EPA Response:**

The response to this comment is acceptable.

***Section 4.3, Building 3 (SWMU 19), Page 18***

4. For consistency with Table 15, this section should be clarified to note that two salty hazardous wastewater tanks (T-1245 and T-1226) were stored outside Building 3 and within a concrete containment dike.

**BMSMC Response:**

Section 4.3 has been revised to include reference to the two salty hazardous wastewater tanks (T-1245 and T-1226) located outside Building 3 and within a concrete containment dike.

**U.S. EPA Response:**

The response to this comment is acceptable.

***Section 4.4, Building 5 (SWMU 20), Page 19***

5. There appears to be some inconsistency with regard to dates of operation between the text of this



section and Table 15. Confirm and clarify when various process wastewater storage features were used at Building 5.

**BMSMC Response:**

The text in Section 4.4 has been revised to state that between 1974 and 1987, hazardous process wastewater was stored adjacent to Building 5 in below ground stainless steel tanks. The text in Section 4.4 was also revised to state that from 1987 to 2007, hazardous process wastewater was stored adjacent to Building 5 in stainless steel tanks located within concrete containment vaults.

**Table 16** (former Table 15) has been revised to show the operational period of two waste tanks designated as T-867 and T-834 ended in 2007.

**U.S. EPA Response:**

The response to this comment is acceptable.

***Section 4.6, Former Tank Farm Area (SWMU 3), Page 19***

6. The first sentence in this section indicates that operations at the Former Tank Farm were discontinued in 1989, but Table 15 puts the shut down in 1990. Confirm the correct date, and correct the RAR accordingly.

**BMSMC Response:**

**Table 16** (former Table 15) has been revised to indicate the operations at the Former Tank Farm ended in 1989. All storage tanks were removed by January 1990.

**U.S. EPA Response:**

The response to this comment is acceptable.

***Section 4.7, North Tank Farm (SWMU 3a), Page 20***

7. The second paragraph in this section suggests that between 1980 and 2007, only methylene chloride and kerosene were stored at the Tank Farm. The text goes on to state that two diesel tanks were then installed in 2012. However, Table 15 indicates that diesel tank V-2419 was in operation in this location from 1980 to 2012. Confirm the dates of operation, and correct the RAR accordingly.

**BMSMC Response:**

The text in Section 4.7 has been revised to indicate diesel storage in tank V-2419 between 1980 and 2012.

**Table 16** (former Table 15) was also revised to indicate the operational period for the Methylene Chloride tanks T-2404, V-2408, V-2410, V-2415, V-2416, V-2418, T-2413 and the kerosene tank T-2403 ended in 2007. These tanks were operational until 2007 and removed from the site in 2009. **Table 16** (former Table 15) has been revised to state the operational period ended in 2007 for these tanks.

**U.S. EPA Response:**

The response to this comment is acceptable.

**Section 5.0, Summary and Conclusions, Page 24**

8. BMSMC recommends that only 1,4-dioxane and naphthalene be reported for SW-846 Method 8270D-Selective Ion Monitoring (SIM). EPA believes it is premature to limit the analyte list at 1-4 dioxane and naphthalene this time. As such this conclusion should be deleted. This issue is discussed further in EPA's September 2016 comments on BMSMC's March and June 2016 Sampling and Analysis Plans for Phases 1 and 2A, respectively.

**BMSMC Response:**

A footnote was added to Section 5.0 to indicate SW-846 Method 8270D SIM was selected for the analysis of Naphthalene and 1,4-Dioxane groundwater samples because this method is capable of providing low detection limits that are less than their respective groundwater RSLs.

**U.S. EPA Response:**

The response to this comment is acceptable.

9. According to Footnote 17, only samples collected from the Building 5 Area will be tested for pesticides. Although Table 14 identifies pesticides as potential new COCs only for that area, the RAR does not explain why pesticide exceedances were limited to this location. Further discussion should be provided with regard to historic and current pesticide usage and storage on the property.

**BMSMC Response:**

A new section, Section 4.16, has been added to the Final Release Assessment Report to discuss historic and current use and storage of pesticides on the property.

As discussed in the March 2016 *Release Assessment Sampling and Analysis Plan*, additional soil and groundwater samples were collected for pesticide analysis from areas outside of the Building 5 Area. Specifically, soil samples collected outside of the Building 5 Area and analyzed for organochlorine pesticides included all downgradient perimeter locations (RA-13, RA-14, RA-15, RA-16, RA-17, RA-18, MW-20S, S-35D, S-39D, S-40S, S-41S, S-42S, and S-43S), one sample collected at the upgradient perimeter boundary (MW-22S), and four randomly selected locations (RA-4, RA-7, RA-10, and SB-102). Groundwater samples collected outside of the Building 5 Area and analyzed for organochlorine pesticides included all shallow and deep downgradient perimeter locations (RA-13, RA-14, RA-15, RA-16, RA-17, RA-18, MW-20, S-35D, S-39, S-40, S-41, S-42, and S-43), each of the upgradient monitoring well locations (MW-21S, MW-22S, and MW-23S) and six randomly selected locations [RA-2 (shallow), RA-4 (deep), RA-5 (deep), RA-7 (shallow and deep), RA-10 (shallow and deep), and SB-102 (shallow and deep)]. Results of the pesticide analysis are presented and discussed in the September 2016 *Release Assessment Phase 1 Technical Memorandum*.

**U.S. EPA Response:** The response to this comment is acceptable.

**Table 3, Additional Hazardous Constituents Detected in Soil Gas**

10. Revise the third footnote to refer to soil gas screening levels, rather than groundwater screening



levels. This same change should also be made in the third footnote to Table 8.

**BMSMC Response:**

The third footnote on **Table 3** and the second footnote on **Table 8** have been changed to refer to soil gas screening levels.

**U.S. EPA Response:**

The response to this comment is acceptable.

***Table 4, Additional Hazardous Constituents Detected in Indoor Air***

11. Revise the third footnote to refer to indoor air screening levels, rather than soil screening levels. This same change should also be made in the second footnote to Table 9.

**BMSMC Response:**

The third footnote on **Table 4** and the third footnote on **Table 9** have been changed to refer to indoor air screening levels.

**U.S. EPA Response:**

The response to this comment is acceptable.

***Table 14, Summary of Hazardous Constituents Present Above Screening Levels***

12. For completeness, this table should be expanded to include all current COCs. For the Former Tank Farm, this table should include acetone, chloromethane, and methyl isobutyl ketone (MIBK). For the Building 5 Area, this table should include acetone, methanol, and MIBK.

**BMSMC Response:**

Acetone, Chloromethane, and MIBK have been added as Former Tank Farm COCs in **Table 14**. Acetone, Methanol, and MIBK have been added as Building 5 Area COCs in **Table 14**. A new footnote has been added to Section 5.0 indicating that current COCs for the Former Tank Farm and Building 5 Area have been added to **Table 14**.

**U.S. EPA Response:**

The response to this comment is acceptable.

13. A footnote should be added to this table to clarify that soil gas and indoor air quality data were unavailable for reassessment with regard to the Former Brule Incinerator. Without such a footnote, these media appear to be of no concern at SWMU 9.

**BMSMC Response:**

A new footnote has been added to **Table 14** that indicates soil gas and indoor air quality data were unavailable to evaluate the vapor intrusion pathway associated with the Former Brule Incinerator. The footnote also states the vapor intrusion pathway associated with the former Brule Incinerator is being evaluated as part of the on-going site-wide vapor intrusion assessment.



**U.S. EPA Response:**

The response to this comment is acceptable.

***Table 15, Characteristics of Storage, Use, and Management Areas for Potential New COCs***

14. The sixth row on page 11 of 12 should be revised to correctly refer to kerosene storage in tank T-2403.

**BMSMC Response:**

The sixth row on page 11 of 12 in **Table 16** (former Table 15) has been revised to correct the spelling of “kerosene”.

**U.S. EPA Response:**

The response to this comment is acceptable.

***Figure 3, Storage, Use and Management Areas That Historically Contained Potential New COCs***

15. In accordance with the information provided in Section 4.0 (page 17) and on Table 15, amend this figure to highlight Building 10 in pink.

**BMSMC Response:**

Building 10 listed in Section 4.0 and discussed in Section 4.12 refers to the Former Building 10 which was used as a drum storage building from the early 1970s to 1994. Former Building 10 was located on the west side of the Facility and north of Former Building 1 and is highlighted in **Figure 7** (former Figure 3) as a storage, use, or management area that historically contained COPCs. The text in Section 4.0 and **Table 16** (former Table 15) has been revised to refer to Building 10 as Former Building 10.

There is a currently-operated building (denoted Current Building 10) which is a 600 square foot storage shed. Current Building 10 that was constructed in 2001 as an aboveground, open-air metal structure with a concrete floor and concrete containment dike. Current Building 10 is presently used for drum and container storage by the maintenance department for lubricant oils and water additives. Based on the presence of a concrete floor with a secondary containment system in good condition and no reports of releases on spill logs, Current Building 10 is not considered a source of COPCs and is therefore not included in the Final Release Assessment Report.

**U.S. EPA Response:**

The response to this comment is acceptable.